Learning objectives

- Provide an overview of TB lab activities in the USAPI
- Demonstration on the proper use of the sputa collection device
- Explain steps for quality sputum collection for effective TB lab diagnosis
- Describe TB lab documents
  - Demonstrate proper completion of the AFB Smear Microscopy and Genexpert Request Form
  - Describe the TB Lab Quarterly Workload Statistics and Performance Indicator Form
  - Describe external quality assessment for TB lab activities in the USAPI
- Discuss general TB lab issues/challenges for improvement

Overview of TB lab activities in the USAPI
Oct 2017 – June 2018
Overview of TB lab testing in the USAPI

LEVEL 1
Sputum smear (direct)

LEVEL 2
痰培(痰培养)

LEVEL 3
痰液培养

AFB smear (direct)

Specimen packing & shipping

MTB Culture DST

Genotyping/ fingerprinting

NAAT

Mycobacteriology Lab
CDC, Atlanta/Other labs

Diagnosis Lab Services
Honolulu, HI

USAPI Labs

Overview of TB lab testing in the USAPI

TB Testing at the Local Lab (Level 1)

AFB Smear Microscopy
(detects the infectious stage of TB)
Duration of process (receipt to reporting) = 30 mins/specimen

1. Sputum smear preparation
2. Sputum smear staining (Ziel Neelsen (ZN) staining)
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific

November 27-30, 2018

3. Drying of smears

4. AFB microscopy
   (100x objectives with oil immersion)

AFB smear results shall be reported according to the WHO guideline as indicated below:

<table>
<thead>
<tr>
<th>AFB Counts</th>
<th>Recording/Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB in at least 100 fields</td>
<td>No AFB Seen/Negative</td>
</tr>
<tr>
<td>1 – 9 AFB in 100 fields</td>
<td>Indicate Actual AFB Count</td>
</tr>
<tr>
<td>10 – 99 AFB in 100 fields</td>
<td>1+</td>
</tr>
<tr>
<td>1 – 10 AFB per field in at least 50 fields</td>
<td>2+</td>
</tr>
<tr>
<td>&gt;10 AFB per field in at least 20 fields</td>
<td>3+</td>
</tr>
</tbody>
</table>

AFB Result Turn-around-Time (TAT) = 24 hrs

Genexpert TB Testing

Genexpert Result Turn-around-Time (TAT) = 2 hrs

AFBs (red-pink rods)

AFB (red-pink rods)

https://www.currytbcenter.ucsf.edu
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific

November 27-30, 2018

USAPI TB Lab Workload

Total number of patients submitting TB specimens for testing between October 2017 – June 2018

<table>
<thead>
<tr>
<th>Area</th>
<th>2017-Q4</th>
<th>2018-Q1</th>
<th>2018-Q2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>201</td>
<td>200</td>
<td>204</td>
</tr>
<tr>
<td>CHK</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>CNMI</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>EBE</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>GUA</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>MAJ</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>PAL</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>PNI</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>YAP</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
</tbody>
</table>

USAPI TB Lab Workload

Total number of specimens processed between October 2017 – June 2018

<table>
<thead>
<tr>
<th>Area</th>
<th>2017-Q4</th>
<th>2018-Q1</th>
<th>2018-Q2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>CHK</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>CNMI</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>EBE</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>GUA</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>MAJ</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>PAL</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>PNI</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
<tr>
<td>YAP</td>
<td>200</td>
<td>205</td>
<td>204</td>
</tr>
</tbody>
</table>

Training

- TB lab refresher training in Palau and Kosrae
  - Additional lab staff trained
  - In-house blind slide rechecking of AFB smears
  - Revision of TB lab manual

- CE sessions completed – Enhancing quality TB specimen collection
  - American Samoa, Ebeeye, Majuro, Kosrae, Palau (PIHOA)
  - Guam (GPHL TB lab staff)
  - Local TB lab updates to clinicians per quarter recommended

- Training of Trainers of Shippers – IATA re-certification training
  - As of Aug 7th 2018  15 IATA shipping trainers; 65 shippers in the USAPI
    - 1 – 2 trainers per lab
    - 1 – 4 shippers per lab

Quality Sputum Collection for TB Testing in the US-affiliated Pacific Islands

https://www.currytbcenter.ucsf.edu
**TB specimen shipping to DLS, Honolulu**
- On going TB shipping \(\rightarrow\) negligible shipping incidents
  - As of Aug 7th 2018 \(\rightarrow\) 15 IATA shipping trainers; 65 shippers in the USAPI

**TB lab external quality assessment (EQA)**
- Genexpert testing
- AFB smear microscopy
- Blind slide rechecking (BSR)

---

Contents of CE sessions completed to enhance quality TB specimen collection (important feedback to TB Program/TB clinicians/DOT workers)

**EXAMPLE**

**TB specimen quality status at Majuro Hospital**

**Jan – Sept 2017**

<table>
<thead>
<tr>
<th></th>
<th>1st Quarter</th>
<th>2nd Quarter</th>
<th>3rd Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # TB suspects</td>
<td>71</td>
<td>68</td>
<td>82</td>
</tr>
<tr>
<td># Patients with 3 specimens</td>
<td>60 (84%)</td>
<td>51 (75%)</td>
<td>56 (68%)</td>
</tr>
<tr>
<td># Patients with 2 specimens</td>
<td>8 (12%)</td>
<td>8 (12%)</td>
<td>14 (17%)</td>
</tr>
<tr>
<td># Patients with 1</td>
<td>3 (4%)</td>
<td>9 (13%)</td>
<td>12 (15%)</td>
</tr>
</tbody>
</table>

**Target** = 100% of TB suspects submitting 3 specimens

0% of TB suspects submitting 2 or 1 specimen

---
Submission of salivary sputum specimens from TB suspects

<table>
<thead>
<tr>
<th>Year</th>
<th>1st Quarter</th>
<th>2nd Quarter</th>
<th>3rd Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>17</td>
<td>24</td>
<td>14</td>
</tr>
</tbody>
</table>

- Total # scored as saliva: 17, 24, 14
- Suspects/Dx: 14 (83%), 19 (79%), 10 (71%)
- Follow-up/Treatment: 3 (17%), 5 (21%), 4 (29%)

Target = 0% of salivary specimens

Proper use of the sputa collection device

1. Demonstration by a DOT worker/TB nurse
2. Demonstration by facilitator

Collection of a quality sputum sample for TB investigation

Recommended: Sputum collection device and container

https://www.currytbcenter.ucsf.edu
Steps for quality sputum collection for effective TB lab diagnosis

1. Enhancing the collection of a quality TB sputum specimen is contributed by:
   
   1. Teamwork
      - Knowing who’s who in the team
      - Knowing your responsibilities and performing to the best of your ability
   
   2. Tools
      - Having an adequate supply of the right tools (specimen containers, etc.) to perform the tasks at hand
      - Having an adequate supply of the right tools
      - Having a good support system in place (internet, networking, etc.)
   
   3. Test
      - Testing technician effectively checks quality of specimen received
   
   4. Time
      - Consistent timely communication among team members on status of sputum quality

2. Collection of quality TB specimens are the responsibility of:

   1. Patient
      - Coached to produce the best quality specimen
      - Provided the correct instructions for collection

   2. TB DOTS worker/nurse
      - Coach the patient to collect the best quality sputum specimen Patient's coach
      - Provide the appropriate sputum collection container
      - Ensure specimen container is tightly capped and correctly labeled
      - Ensure completion of the lab request form
      - Timely delivery of the TB specimen & lab request form to the laboratory

   3. TB lab technician
      - Receives and ensures specimen matches information on the lab request form
3. How can you help obtain quality sputum specimens?

**Clinician**
- Use the right specimen container: Sputum collection device is provided by DLS.
- Training: Coach patient in sputum specimen collection.
- Good instructions to patient:
  - DOT/Nurses and patients to train on how to use the sputum collection device.
  - Patient to rinse mouth before collecting sputum.
  - Collect >5mL of sputum.
  - Ensure collection of 3 specimens from TB suspects.
- Good documentation: Take time to adequately complete the lab requisition form.

**Laboratory**
- Good documentation: Take time to adequately correlate the specimen with the lab requisition form.
- Store specimens at 4°C.
- Refrigerate specimens for field DOT workers can use small ice boxes with cold ice packs.
- Ship sputum ASAP: Do not hold sputum at clinic/ward, TB lab tech to ship specimen ASAP.

4. Coaching of patient in the sputum collection very important

1. Clear your mouth.
2. Breath in and out 2 times.
3. Give a sputum sample.
5. The best sputum specimen

**YES**
- Muco-purulent sputum

**NO**
- Salivary sputum

**Recommended volume: >5mL**

---

Muco-purulent sputum vs Salivary sputum

**YES**
- Epithelial cells

**NO**
- White cells

---

AFBs clustered around or within dead white cells (pus cells)

**YES**
- AFBs in or around white cells

**NO**
- White cells

---

https://www.currytbcenter.ucsf.edu
Main issues for collection of quality sputum in the USAPI

1. High saliva content
2. Inadequate volume (< 5mL)
3. Over 10 days storage of sputum specimens before shipping to DLS
4. Contaminated sputum from betel nut chewers
5. Incomplete TB lab requisition forms
6. Delivery of leaking sputum specimens to the laboratory
7. Mislabeled specimens
8. Collection of sputum in inappropriate specimen containers
9. Collection of sputum in non-sterile containers
10. Un-refrigerated sputum specimen after collection
11. Non-submission of 3 specimens from diagnostic/suspect TB patients

Impact of these issues on TB testing & results

1. High saliva content: Low chances of detecting the AFBs
2. Inadequate volume (< 5mL): Volume inadequate to do several other tests at DLS
3. Over 10 days storage of sputum specimens before shipping to DLS: Contaminants overgrowth increases, AFB growth viability decreases
4. Contaminated sputum from betel nut chewers: Contaminants overgrowth increases, AFB growth viability decreases
5. Incompletely filled TB lab requisition forms: Specimen will be rejected and not processed
6. Delivery of leaking sputum specimen to the laboratory: Specimen will be rejected
7. Mislabeled specimens: Specimen will be rejected
8. Collection of sputum in inappropriate specimen containers: Transfer of sputum may leave some sputum in the old container, exposure to contaminants increased
9. Collection of sputum in non-sterile containers: Other bacterial contaminants may overgrow AFB growth
10. Un-refrigerated sputum specimen after collection: Low chances of recovery of Mtb
11. Submission of 1-2 specimens: Low chances of detecting the AFBs
Other recommended specimen types & volumes required for AFB testing

- CSF – 3mL
- Urine – 40mL
- Stool – 1g
- Gastric lavage/washing fluid – >5 - 10mL
  - Collect in the morning soon after patient awakens in order to obtain sputum swallowed during sleep.
  - Collect fasting early morning specimen on three (3) consecutive days. Use sterile water.
  - Adjust to neutral pH with sodium carbonate immediately after collection.
- Label the container with the patient’s full name.
- Label the container with the “Gastric lavage/washing”.
- Place into the biohazard bag and seal it.
- Store at 2 – 8°C if transport to the lab is delayed for more than 1 hour.
- Specimen should be transported or shipped to the lab at 2 – 8°C.
- Neutralization is a critical step in preserving the integrity of this specimen type.
- No specimen will be rejected. However, specimens that are not neutralized will be tested on Genexpert MTB/RIF at DLS and reported.

What constitutes a quality TB specimen delivered to the lab?

- Muco-purulent sputum specimen
- Free of betel nut and food particles
- 3 specimens (if TB suspect)
- Volume of >5mL
- Correctly labeled specimen container
- Tightly capped specimen container
- Correctly completed ‘AFB smear microscopy and Genexpert Request Form’
- Timely delivery to the lab

TB lab documents & records
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific  
November 27-30, 2018

### TB lab documents and records

- Various types of TB lab documents and records
- Each document relates to the type of TB lab activity involved
- Types of TB lab documents and related activities:

1. **TB Standard Operating Procedure (SOP) Manual**
   - Documents test methods
   - TB lab manuals are 5 years old or more
   - Need review and update to reflect current practice

2. **AFB Smear Microscopy and Genexpert Request Form**
   - Specimen receipt
   - Testing & reporting
   - Revised version will be used from Jan 2019

3. **TB Register**
   - Lab registration of specimen
   - Recording of TB lab results
   - Each patient’s specimen results need to be completed (e.g. DLS TB culture results)
   - Compilation of TB lab quarterly reports

4. **TB Lab Quarterly Workload Statistics and Performance Indicator Form**
   - Compilation of TB lab quarterly reports
   - Revised version will be used from Jan 2019

5. **TB specimen manifest & other shipping documents (TB shipping protocol, AFB, etc.)**
   - TB specimen shipping

6. **Problem log**
   - Specimen rejection
   - Existence of problem logs in some labs
   - Review and share with TB program in your scheduled TB program meetings

### Description revised lab documents

- AFB Smear Microscopy and Genexpert Request Form (version-Nov 2018)
- TB Lab Quarterly Workload Statistics and Performance Indicator Form (version-Nov 2018)
- Group exercises
Comparison of Performance Indicators across the USAPI labs: October 2017 – June 2018

Note: Top figure not available for 2017-Q4

Positivity rate among specimens between October 2017 – June 2018

Positivity rate among TB patients between October 2017 and June 2018

Quality Sputum Collection for TB Testing in the US-affiliated Pacific Islands 13
https://www.currytbcenter.ucsf.edu
Proportion of specimens scored as saliva between October 2017 – October 2018

Total # of specimens vs average TAT % October 2017 – June 2018

External quality assessment (EQA) for TB lab activities in the USAPI
External Quality Assessment (EQA)

- “EQA is a system for objectively checking the laboratory's performance using an external agency or facility” — (WHO)

Laboratory Quality Management System (LQMS)

Implementing Quality Management does not guarantee an ERROR-FREE Laboratory

But it detects errors that may occur and prevents them from recurring

Laboratories not implementing a quality management system guarantees UNDETECTED ERRORS
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific

Quality Sputum Collection for TB Testing in the US-affiliated Pacific Islands

https://www.currytbcenter.ucsf.edu
On-site lab assessment

- An assessment of the real situation onsite
- A better view of current lab practices
- An opportunity to interview lab staff if needed
- An opportunity to consult with lab management to rectify or correct any inadequate practices or situations if encountered

Importance of EQA in TB lab testing

- Participation in an external quality assessment program provides valuable data and information which:
  - allows comparison of performance and results among different test sites;
  - provides early warning for systematic problems associated with kits or operations;
  - indicates areas that need improvement (reliability of methods, materials, equipment) and develop and implement corrective actions;
  - identifies training needs and monitor training impact
  - creates a network for communication
  - a good tool for enhancing a national laboratory network
  - samples received for EQA testing are useful for conducting continuing education activities

- EQA helps to assure customers, such as physicians, patients, and health authorities, that the laboratory can produce reliable results.

- EQA participation → a requirement for lab accreditation.

Overview of TB lab testing in the USAPI

- AFB smear (direct)
- AFB smear (sedimentation)
- Specimen packing & shipping
- NAAT
- MTB Culture & DST
- Genexpert
- Genotyping/ Fingerprinting
- LEVEL 1 USAPI labs
- LEVEL 2 Diagnostics Lab Services Managed by CDC
- LEVEL 3 Mycobacteriology Lab CDC, Atlanta
- LEVEL 2 Genexpert Lab Services
- LEVEL 3 Genotyping/ Fingerprinting

https://www.currytbcenter.ucsf.edu
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific

November 27-30, 2018

TB Laboratory EQA Activities in the USAPI

Comparison of TB Lab EQA Performance among the USAPI labs: 2016 - 2017

Acid-fast bacilli staining & microscopy PT
Blind-slide rechecking (BSR)
Genexpert PT

Total number of specimens processed between October 2017 – June 2018
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific

November 27-30, 2018

Quality Sputum Collection for TB Testing in the US-affiliated Pacific Islands

https://www.currytbcenter.ucsf.edu
References

- [http://www.who.int/ihr/training/laboratory_quality/10_b_eqa_contents](http://www.who.int/ihr/training/laboratory_quality/10_b_eqa_contents)
- [http://www.who.int/ihr/training/laboratory_quality/11_cd_rom_tb_eqa_wpro.pdf](http://www.who.int/ihr/training/laboratory_quality/11_cd_rom_tb_eqa_wpro.pdf)

General TB lab issues/challenges for improvement

Medical Lab Workforce – TB Lab Section

Current status:

- 1 – 2 TB lab staff in each lab (with supportive back-up)
- PCSI Lab Coordinators (Palau & RMI-Majuro)

Training

Upcoming plans:

- Professional development of TB lab techs
  - Annual professional development (online) for USAPI TB lab techs
  - Adoption of TB lab technician core competency requirements (+8) by all other USAPI labs
  - TB lab training in Pohnpei and any other lab (determined by the 2018 EQA results)
Identify, Evaluate, and Treat! Steps to Improve TB Contact Investigation in the Pacific

November 27-30, 2018

- Reporting of 4+ AFB smears by DLS
- Only report sedimented TB sputum specimens (not for AFB PT panels)

- Gastric lavage specimens
  - NEED TO BE NEUTRALIZED FOR BEST RESULTS!!!
  1. Are all gastric lavage specimens received in the lab correctly labelled as such?
  2. Are gastric lavage specimens being neutralized at the collection site?
  3. Do you have sodium carbonate for neutralizing gastric lavage specimens?

<table>
<thead>
<tr>
<th>Q#</th>
<th>Chuuk</th>
<th>Ebeye</th>
<th>OIG</th>
<th>Saipan</th>
<th>Pohnpei</th>
<th>Kosrae</th>
<th>Pohnpe</th>
<th>Majuro</th>
<th>Yap</th>
<th>GPHL A/</th>
<th>Samoa</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>N/A</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>3</td>
<td>N/A</td>
<td>N/A</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Upcoming plans:

- How do you prefer to handle neutralization of gastric lavage specimens? ➔ for discussion
- Options:
  1. Neutralize at collection site
     ➔ Prepare sodium carbonate package and deliver to collection site
  2. Neutralize in the lab
     ➔ Collect and deliver GL to lab ASAP
     ➔ Prepare sodium carbonate package and neutralize in lab as soon as GL is received

TB Specimen Shipping

- DO NOT SEND PRE-SHIPPING NOTIFICATIONS TO DLS
- COMMUNICATE! COMMUNICATE! COMMUNICATE!

Reminders:

- Include logistics-dispatch@dlslab.com in your post-shipping email notification
- For all DLS shipments:
  - Indicate on AWB under 'Handling Information':
  - "PLEASE CONTACT DLS DISPATCH UPON ARRIVAL. TELEPHONE: 808 589-5103"
Thank you!!

vasitiu@pihoa.org